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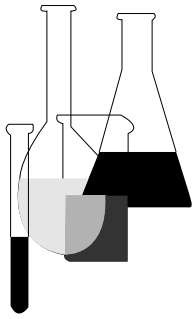
Residue Chemistry Test Guidelines

OPPTS 860.1460
Food Handling



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

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OPPTS 860.1460 Food handling.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 171–4 Results of Tests on the Amount of Residue Remaining, Including A Description of the Analytical Methods Used (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, EPA Report 540/09-82-023, October 1982). This OPPTS guideline should be used in conjunction with OPPTS 860.1000, Background.

(b) **Purpose.** Studies must be conducted to determine residues in food or feed resulting from treatment of food/feed handling establishments with pesticides.

(c) **Definitions.** Terms used in this guideline have the meanings set forth at 40 CFR l62.3 and at 40 CFR part 158. In addition, for the purposes of this guideline, the following definitions apply:

Crack and crevice treatment is application of small amounts of pesticides into cracks and crevices in which pests hide or through which they may enter a building. Such openings commonly occur at expansion joints, between different elements of construction, and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits, motor housings, and junction or switch boxes.

Food areas of food handling establishments include areas for receiving, serving, storing (dry, cold, frozen, raw), packaging (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), storing edible waste, and enclosed processing systems (mills, dairies, edible oils, syrups).

A *food handling establishment* is an area or place other than a private residence in which food is held, processed, prepared, and/or served.

General treatment is application to broad expanses of surfaces such as walls, floors, and ceilings, or as an outside treatment.

Nonfood areas of food handling establishments include garbage room, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling).

Space treatment is the dispersal of pesticides into the air by foggers, misters, aerosol devices or vapor dispensers for control of flying pests.

Spot treatment is application to limited areas where pests are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. Those areas may occur on floors, walls, and bases or undersides of equipment. For this purpose, a ''spot'' will not exceed 2 ft^2.

(d) **Procedure.** (1) Establishments to be treated will be typical commercial operations selected from among the various types listed under each of the categories shown in the following Table 1.:

Table I—Categories and Representative Types of Food Handling Establishments

Category	Representative Types
Food services[1]	Restaurants, cafeterias, taverns, delicatessens, mess halls, school and institutional dining areas, hospitals, mobile canteens, vending machines, grocery stores and markets.
Manufacturing establishments[2]	Plants engaged in the manufacture of candy, ice cream, spaghetti or macaroni, food mixes, or breakfast cereal and bakeries, breweries, wineries, soft drink bottling plants, pizza plants.
Processing establishments[3]	Plants engaged in the slaughtering and/or packing of meats, poultry, and seafood; dairies and plants engaged in the processing of dairy products; plants engaged in the processing of spices and herbs, edible fats and oils, beverages (coffee, tea), and frozen fresh food; fruit and vegetable canneries; pickle factories; grain mills.

[1] Any food handling establishment whose principal business involves the sale of food directly to the consuming public. The manufacture and/or processing of food by such an establishment is only incidental to achieving its principal business objective.

[2] Any food handling establishment whose principal business involves the production and/or packaging of man-made foods which are normally intended for sale through or by food service establishments. Such foods generally comprise two or more ingredients which have been altered in such a manner as to change their basic identity.

[3] Any food handling establishment whose principal business involves the upgrading and/or preservation of raw agricultural commodities in such a manner as to maintain their essential identity. Such establishments may sell their product directly to the consuming public and/or food service or food handling establishments.

(2) Data obtained from tests conducted in two different types of establishments in each category will normally be adequate for clearance of the pesticide for use in all types of establishments defined by the category of which the test establishment is a part. Careful judgment will have to be applied in selecting the types of establishments to be tested as well as the number of tests necessary in order to ensure adequate representation of that category. More than two types of establishments may require testing as the individual case indicates. Existing sanitation programs and practices, as well as the type of building construction (wood, cement block, etc.) at a plant site, are important factors that should be considered. Usage will normally involve application of the pesticide as a space, general, spot,

or crack and crevice treatment, and will include both nonfood and food areas of the establishment used as the test site. Acceptable results from a test of the most rigorous type of treatment (space > general > spot > crack and crevice) will preclude need for residue tests involving less rigorous treatments, and will allow registration of the pesticide for use by the less rigorous methods. In fact, in many cases, one thorough study representing worst-case residues will suffice to cover use in all types of establishment. Petitioners are advised to submit a protocol before initiating a residue study intended to support use in food handling establishments. Treatment of establishments for purposes of this test should be performed in accordance with proposed labeling.

(3) The experiment should be designed to reflect all possible avenues of contamination, taking into account the physical and chemical properties of the pesticide, proximity of foods and protective barriers as may be specified in the regulation, mode of application, and use restrictions.

(4) Consideration should be given to at least the following residue transfer routes where applicable:

(i) Direct deposition of spray droplets on foods, direct absorption of fumigant, or airborne dust particles.

(ii) Volatilization of residual deposits and subsequent absorption into foods.

(iii) Direct transfer of residues from treated spaces (countertops, cupboards, utensils, packaging materials, etc.).

(iv) Volatilization with condensation on surfaces where food is subsequently placed.

(v) Leakage or weeping of the chemical from devices or impregnated materials hung in food establishments for pest control.

(vi) Transfer of the pesticide through pesticide barriers (e.g. from impregnated shelf papers to packaged food).

(vii) Tracking of residues from bait stations or sprayed areas to foods or food contact surfaces by pests, or contamination from fallen insects.

(viii) Deposition of solid or crystalline chemicals resulting from repeated sprays on ceilings over food handling areas.

(ix) Distribution of vapors, droplets, or particulate matter through forced ventilation systems (central air conditioning, duct heating systems).

(x) Distribution of residues in continuous process food operations from treatment of ends and tailings, conveyor lines, boats, etc, when operation is shut down (e.g. flour mills).

(5) Many sources of contamination may be eliminated (or greatly diminished) through restrictions, variations in the mode of application, type of establishment treated or nature of the product or formulation. Data should be submitted to establish the relative importance of these factors on the levels of residue which may be expected to result from the pesticidal application. Experiments should be conducted by analyses of representative foods subjected to exposure by any of the above routes which are potential avenues of contamination.

(6) The selection of samples for analyses in the more specialized uses, e.g. flour mills, would be apparent. In the more generalized exposure situations, e.g. grocery stores, it is suggested that the selection of samples for analyses represent a range of foods such as an oily food (e.g. butter), baked cereal products (e.g. bread), beverages (e.g. milk), raw and processed meats, and fresh fruits and vegetables (e.g. lettuce).

(7) In order to demonstrate the residues resulting from the wide variation of conditions anticipated in actual situations, and to gauge the potential for misuse, the experiment should include some exaggerated exposure. This might include spraying at a 2× rate, exposure of foods for longer periods than might normally be expected, or even exposure of some foods when there is a restriction to cover foods when treating.